IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
BALTIMORE DIVISION

UNITED STATES OF AMERICA; THE STATES OF CALIFORNIA, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, and WISCONSIN; COOK COUNTY, ILLINOIS; THE CITIES OF CHICAGO and NEW YORK; and the DISTRICT OF COLUMBIA ex rel. BARRY ROSTHOLDER and BARRY ROSTHOLDER, individually, Plaintiffs, v. OMNICARE, INC., a Delaware Corporation; OMNICARE DISTRIBUTION CENTER, LLC, f/k/a HEARTLAND REPACK SERVICES, LLC, a Delaware Limited Liability Company, jointly and severally, Defendants.	Case No. CCB-07-1283 Honorable: Catherine C. Blake

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SECOND AMENDED COMPLAINT FOR VIOLATION OF THE FEDERAL FALSE CLAIMS ACT (31 U.S.C. §§ 3729 *et seq.*)
TRIAL BY JURY REQUESTED

Pursuant to 31 U.S.C. § 3730(b)(1) and the False Claims Acts of the States, County, Cities and District, as defined and more specifically listed below, Barry Rostholder, for himself and on behalf of the United States of America; the states of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas,

Virginia and Wisconsin (collectively, the "States"); the District of Columbia (the "District"); Cook County, Illinois (the "County"); and the cities of Chicago and New York (collectively, the "Cities"), through his attorneys, Cohan and West P.C., Frank, Haron, Weiner and Navarro P.L.C., and Hellmuth & Johnson, PLLC, brings this civil action under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, the False Claims Act of the above-listed States, County, Cities and District.

INTRODUCTION

This case arises from the actions of Defendant Omnicare, Inc. and its partner Health Care Resources ("HCR") in knowingly (with actual knowledge, or deliberate ignorance or reckless disregard for the truth) causing pharmaceuticals to be dangerously adulterated and misbranded, and then distributed and administered to as many as 1.4 million elderly residents of skilled nursing facilities and assisted living facilities nationwide, most of which were owned by HCR Manor Care. Adulterated and misbranded drug products are not in their FDA-approved form, which is a requirement for coverage of drug products under government healthcare programs and plans. Therefore, Defendants herein knowingly (with actual knowledge, or deliberate ignorance or reckless disregard for the truth) presented, or caused to be presented, to federal and state governments claims for payment of drugs that were ineligible for payment.

In particular, Defendant Omnicare acted directly and/or via a wholly-owned subsidiary, Doe Corporation 1, and in a partnership with HCR, to operate a large dispensing pharmacy that manually packaged and dispensed penicillin and other beta-lactam antibiotics in such a manner as to kick-up considerable amounts of beta-lactam dust into the ambient air of the building, which then coated all surfaces with beta-lactam residue. These actions violated the Food Drug & Cosmetic Act ("FD&CA"), and the Food and Drug Administration's ("FDA") implementing

regulations, which include compliance with current good manufacturing practices ("cGMP"). Those laws require penicillin and other beta-lactam drugs to be handled in such a manner as to prevent cross-contamination to other drugs and, if a "reasonable possibility" exists that cross-contamination may have occurred, then the non-penicillin drugs are presumed to be adulterated and unfit for interstate commerce unless testing re-establishes their safety. No such testing was done, yet said Defendants dispensed the drugs into interstate commerce, whereafter the federal and state governments paid Defendants and others for over half of those drugs despite the drugs' ineligibility of coverage.

The building also housed other business units handling even larger volumes of drugs that were thus subjected to a "reasonable possibility" of cross-contamination, yet were never tested before being distributed in interstate commerce and billed to the government. In particular, Defendant Omnicare, directly and/or via a wholly-owned subsidiary, Defendant Heartland Repack Services, LLC, and at times in partnership with HCR, operated a very large automated pharmaceutical blister-packing facility in the same building where Omnicare and its partner HCR operated the large pharmacy that manually repackaged penicillin and other beta-lactam pharmaceuticals. The automated facility packaged over 200 million doses annually, and provided drugs to up to 1.4 million patients, mostly residents of HCR nursing homes, which were the ultimate "client" served by the automated repackaging facility. Said Defendants did so without complying with the requisite FD&CA and FDA laws requiring separate air handling equipment, separate employee entrances, and other safeguards against beta-lactam contamination in the automated blister-packing part of the building. Again, no testing to re-establish safety as against beta-lactam cross-contamination was ever done. Nonetheless, said Defendants

distributed the drugs in interstate commerce, whereafter the federal and state governments paid Defendants and others for over half of those drugs despite the drugs' ineligibility of coverage.

The risk of cross-contamination was more than theoretical, as found by the FDA in 2006 when it closed the automated repackaging facility, quarantined the inventory and required re-testing due to beta-lactam residues found throughout the building. Defendants themselves conducted tests at that time and found beta-lactam residue throughout the automated repacking facility. Rather than test $18.9 million in quarantined drug inventory, Defendants chose to dispose of it and write it off. By doing so, Defendants avoided creating any scientific data concerning the actual level of beta-lactam contamination on that inventory, and then spoliated the raw evidence.

Defendants acted at all times with actual knowledge, or deliberate ignorance or reckless disregard for the truth. Through Defendants' actions of causing adulterated and misbranded pharmaceuticals to be distributed to long-term care facilities, Defendants not only violated the FD&CA, FDA regulations and the federal False Claims Act, but also endangered the safety of the 1.4 million elderly patients served by Defendants. Such unlawful acts damaged the integrity of the process by which pharmaceuticals of known safety and efficacy are delivered to needy seniors, and also caused federal and state health care programs to make improper payments for adulterated and misbranded products that were ineligible for payment.

JURISDICTION AND VENUE

1. This action arises under 31 U.S.C. §§ 3729 *et seq.*, also known as the False Claims Act ("FCA"), as well as the False Claims Acts of the States, County, Cities and District (hereafter referred to collectively as the "State FCAs"), to recover treble damages and civil

penalties on behalf of the United States of America arising out of Defendants' violations of the FCA and State FCAs.

2. Under § 3732 of the FCA, this Court has jurisdiction over actions brought under the Act and concurrent jurisdiction over the State FCAs. Furthermore, jurisdiction over this action is conferred on this Court by 28 U.S.C. § 1331 because this civil action arises under the laws of the United States.

3. This Court has supplemental jurisdiction over all other claims set forth in this Complaint because these claims are so related to the claims arising under the federal False Claims Act that they form part of the same case or controversy. *See* 28 U.S.C. § 1367.

4. Venue is proper in this district pursuant to § 3732(a) of the FCA, which provides that "any action under § 3730 may be brought in any judicial district in which the Defendant or, in the case of multiple Defendants, any one Defendant can be found, resides, transacts business, or in which any act proscribed by § 3729 occurred."

5. The proscribed acts, which are the subject of this action, occurred nationwide including in the State of Maryland in this judicial district. At all times material hereto, Defendants regularly conducted substantial business within the State of Maryland by making significant sales and/or claims for reimbursement within the State of Maryland, within this judicial district. Additionally, venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(1)-(2).

FILING UNDER SEAL

6. Under the FCA, as well as the State FCAs, the original complaint was filed *in camera* and remained under seal for a period of at least sixty (60) days and shall not be served on the Defendants until the Court so orders. The Government may elect to intervene and proceed

with the action within sixty (60) days after the Government receives the Complaint and Disclosure Statement, or at any later time upon a showing of good cause. 31 U.S.C. § 3130(b)(2), (c)(3).

7. As required by the False Claims Act, 31 U.S.C. § 3730(e)(4)(b), Relator is an original source of the information in this Second Amended Complaint. He has direct independent knowledge of the allegations contained in this Second Amended Complaint and has made disclosures of the violations alleged in this Second Amended Complaint to the United States Food and Drug Administration ("FDA"), which, thereafter, commenced an investigation which resulted in the closure of Defendants' pharmaceutical repackaging facility.

PARTIES

8. Barry Rostholder ("Relator") is a resident of Ohio and was previously employed by Defendant Heartland Repack Services, LLC ("Heartland Repack") as Senior Director of Operations for repackaging (in 2008 Heartland Repack Services, LLC was renamed Omnicare Distribution Center, LLC; however for purposes of this complaint, the LLC's prior name will be used). Relator's qualifications included education and licensure as a pharmacist. Relator began his employment with Defendants in 1997 and left in February or March of 2006. During his tenure at Heartland Repack, Relator's responsibilities included overseeing repackaging, quality assurance, regulatory affairs, and wholesale and distribution.[1]

9. Defendant Omnicare Distribution Center LLC, f/k/a Heartland Repack Services, LLC, is a Delaware Limited Liability Company. At all times pertinent to this Complaint it operated under the name Heartland Repack with its principal place of business at 4755 South

[1] Relator was initially responsible for wholesale and distribution; however, this division later stopped reporting to him due to reorganization within the business.

Avenue, Toledo, Ohio 43615. Heartland Repack is owned, operated and controlled solely by Defendant Omnicare, Inc. ("Omnicare").

10. Defendant Omnicare, Inc., is a Delaware corporation with its principal place of business at 100 E. Rivercenter Blvd., Suite 1600, Covington, Kentucky 41011. Omnicare wholly owns Defendant Omnicare Distribution Center, LLC, f/k/a Heartland Repack Services, LLC. Omnicare was also variously, either directly or through a wholly-owned subsidiary (Doe Corporation 1), a 50% partner with HCR in Heartland Healthcare Services, an Ohio general partnership.

BACKGROUND

False Claims Act

11. The FCA and the State FCAs make it unlawful for any person to directly or indirectly deceive the government in order to receive, retain or avoid returning government money or property. *See* 31 U.S.C. § 3729 *et seq*.; *see also* Counts IV-XXIX for State FCA citations. The FCA and State FCAs are *in pari material* for each other.

12. In particular, liability accrues under 31 U.S.C. § 3729(a)(1) when a person knowingly presents, or causes to be presented, to an officer or employee of the United States Government a false or fraudulent claim for payment or approval. Liability is also imposed under 31 U.S.C. § 3729(a)(2) when a person knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government.

13. Liability is also imposed under 31 U.S.C. § 3729(a)(7) for a "reverse" false claim when a person knowingly makes, uses, or causes to be made or used, a false record or statement to conceal an obligation to pay or transmit money or property to the government.

14. As defined under 31 U.S.C. § 3729(b), "knowing" and "knowingly" means that a person: (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information.

15. Under 31 U.S.C. § 3729(c), a "claim" includes any request or demand, whether under a contract or otherwise, for money which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money which is requested or demanded, or if the government will reimburse such contractor, grantee or other recipient for any portion of the money which is requested or demanded.

16. In accordance with 31 U.S.C. § 3729(a), any individual or entity liable for defrauding the government under the False Claims Act is required to pay the United States government a civil penalty of not less than $5,500 and not more than $11,000 for each claim submitted, plus three times the amount of damages sustained by the government, plus the government's costs of the action.

17. In addition, the liable defendant must also pay the Relator's attorneys' fees, expenses and costs. 31 U.S.C. § 3730(d)(1) and (2). Furthermore, defendants may also be liable to an employee-relator for retaliation, constructive discharge or other unfavorable treatment in connection with Relator's efforts to stand up for the government's rights. 31 U.S.C. § 3130(h).

Medicare

18. Medicare is a federally-funded health care insurance program created in 1965 by Title XVIII of the Social Security Act, and provides insurance coverage for people over the age of 65 and people with disabilities. It is administered by the Centers for Medicare and Medicaid

Services ("CMS"), which is a division of the United States Department of Health and Human Services ("HHS").

19. Medicare Part A pays for, *inter alia*, items and services provided to hospital inpatients, home health care patients, and for patients of Skilled Nursing Facilities ("SNFs"). A SNF provides skilled care to a patient after an injury or a hospital stay if the patient meets certain conditions, and may be part of a nursing home or hospital. Medicare pays for up to 100 days of care provided to SNF patients using a "Prospective Payment System" ("PPS").

20. Under PPS, a skilled nursing facility receives a "bundled" payment for all services and items provided to an SNF patient covered by Medicare Part A. The "bundled" payment is an estimate of the costs for all lodging, meals, skilled nursing care, physical therapy, medications, social services, and other qualified treatments based, in part, on actual cost data submitted by each SNF in its annual Cost Report. In the Cost Report the SNF must properly differentiate between "allowable costs" and "non-allowable costs" incurred. Allowable costs include FDA-approved drugs, but not drugs whose safety was uncertain and therefore not in their FDA-approved form.

21. Medicare will pay for care provided to SNF patients for up to 100 days, after which time the patient assumes responsibility for the costs. If the patient does not have the financial means to pay, then the costs are covered under Medicaid.

22. Medicare Part B is a federal program that covers physician services and certain injectable, inhalation and infused drugs administered by the health care provider.

23. Medicare Part C, also known as Medicare Advantage ("MA"), allows Medicare Part A and B eligibles to pay premiums to a provider network and receive their covered services through that network. The government pays the provider a monthly capitated amount to provide

Medicare Part A and Part B items and services to the enrolled beneficiaries. For an additional premium, most plans also offer Medicare Part D outpatient drug coverage, and are known as MA-PD plans. Whether ultimately paid by the government directly or on a capitated basis, the government imposes certain reporting requirements to ensure that it is only paying for eligible drugs.

24. Medicare Part D began January 1, 2006 and pays for prescription drug benefits for the elderly and disabled. Part D requires beneficiaries to enroll and pay certain premiums, deductibles, co-payments, and even 100% of drug costs after a certain dollar threshold and up to a maximum dollar amount (the "donut hole"), that then triggers catastrophic coverage. The federal government pays 75% of actual costs between the deductible and the donut hole, and 95% of catastrophic coverage. For low-income individuals there are various tiers in which the government pays greater percentages, up to a 100% subsidy which may be capitated.

25. If a person is dually eligible for Medicaid and Medicare, their outpatient drugs are covered by Medicare Part D. Thus, except when a patient is covered under Medicare Part A, after January 1, 2006 drugs for qualifying SNF patients were covered under Medicare Part D even if the remainder of their care was covered under Medicaid.

26. Under Part D, the government advances funds to the Part D Provider ("PDP") on a monthly basis according to the PDP's accepted bid. As an express condition of payment under Medicare Part D, for each prescription dispensed to one of its Part D enrollees, the PDP must submit to Medicare certain "prescription drug event data," including the price paid by the PDP. The required data is used in the year-end reconciliation process designed to ensure that the government ultimately only pays for the actual cost of FDA-approved drugs dispensed to enrolled beneficiaries.

27. Medicare Part D expressly defines covered drugs by adopting the definition set forth in Medicaid requiring that the drug meet all the requirements and conditions of FDA-approval, which expressly include compliance with cGMP regulations. 42 C.F.R. § 423.100 (defining "Part D drug"). Thus, under Medicare Part D regulations, it is unlawful for a pharmacy to "dispense drugs that are expired, **or have not been stored or handled in accordance with manufacturer and FDA requirements**." *See* Prescription Drug Benefit Manual, Chapter 9 – Part D Program to Control Fraud, Waste and Abuse, Section 70.1.3.

28. As to all Parts of Medicare, Section 1862(a)(1)(A) of the Social Security Act (42 U.S.C. § 1395y) requires that drugs must be reasonable and necessary in order to be covered under Medicare. **This means the FDA must have approved them for marketing and that all steps of production and handling complied with cGMP** to ensure their safety and efficacy, and to permit introduction of the drug product into interstate commerce**.** *See* Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, Section 50.4.7.

Medicaid

29. Medicaid is a medical assistance program jointly financed by states and the federal government for low-income individuals and is embodied in Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq.* The Medicaid program enables states to provide assistance for necessary medical services to low-income persons. Through December 31, 2005, persons dually eligible under Medicaid and Medicare had their outpatient drugs covered by Medicaid. As to covered outpatient drugs, pharmacies and other providers submit claims directly to the relevant state Medicaid agency's fiscal intermediary, which then pays the claims according to that state's approved Medicaid covered drug payment schedule.

30. The states' discretion in administering the program is limited by federal laws and regulations, including the general requirement that all medical payments must be for reasonable and necessary services. Furthermore, Medicaid expressly limits coverage of outpatient drugs to those that meet all the requirements and conditions of FDA-approval, which expressly include compliance with cGMP regulations. 42 U.S.C. § 1396r-8(k)(2)(A)(i).

31. At all times relevant to this complaint, the United States provided federal funds to the Medicaid programs of the states within Defendants' service area. Thus, all claims or requests for payments submitted to those states' Medicaid programs are subject to liability under the FCA pursuant to 31 U.S.C. § 3729(c) and all relevant false claims acts enacted by those states

TRICARE/CHAMPVA

32. TRICARE/CHAMPVA is a federally-funded program that provides medical coverage to both active duty and retired members of the uniformed services and their dependents. TRICARE program funds come from a general revenue fund that is appropriated for the Department of Defense. *See* 32 C.F.R. § 199.1(e).

33. TRICARE/CHAMPVA benefits for medical services and out-of-pocket costs are similar to coverage under Medicare. TRICARE eligibility ends when military members or retirees and their dependents turn 65. *See* 10 U.S.C. § 1086(d)(1). Thereafter, coverage is under CHAMPVA.

34. Due to the fact that TRICARE/CHAMPVA is funded by the federal government, any false or fraudulent claim submitted in connection with a payment for medical services under TRICARE/CHAMPVA constitutes a false claim for purposes of the FCA.

Veterans Health Administration

35. The United States Department of Veterans Affairs, via the Veterans Health Administration, provides an extensive network of health care services to veterans for either no cost or a fee.

36. Accordingly, the Veterans Health Administration is authorized to pay for some or all of certain veterans' health care, including pharmaceuticals. *See* 38 U.S.C. § 1703.

37. The United States Department of Veterans Affairs receives funding by the federal government and accordingly any false or fraudulent claim submitted in connection with a payment for medical services constitutes a false claim for purposes of the FCA.

Federal Employee Health Benefit Program

38. The United States Office of Personnel Management oversees the Federal Employees Health Benefits Program, which provides benefits such as health care to full-time permanent civilian employees of the United States Government. *See* 5 C.F.R. § 890.102.

39. To provide health care benefits, the Federal Employees Health Benefits Program coordinates with employee organization plans which, in turn, contracts with individual carriers. In order for a carrier's claim to be proper, the claim must be for actual, reasonable and necessary costs incurred. *See* 48 C.F.R. § 1652.216-71.

40. The Federal Employees Health Benefits Program is partially funded by the federal government, and accordingly any false or fraudulent claim submitted in connection with a payment for medical services constitutes a false claim for purposes of the FCA.

General Legal Principles Applicable to All Federal Programs

41. When a drug product that reaches the consumer is adulterated and/or misbranded and thus not in the form approved by the FDA for marketing and introduction into interstate

commerce, the government "did not receive that which they bargained for – an FDA-approved drug of *known* safety and efficacy," and is entitled to recoup all sums paid for the drug. *U.S. v. Marcus*, 82 F.3d 606, 610 (4th Cir. 1996) (italics in original); *U.S. v. Bhutani*, 266 F.3d 661, 670 (7th Cir. 2001).

United States Food and Drug Administration Requirements

42. The FD&CA prohibits the adulteration or misbranding of any drug for introduction or delivery for introduction into interstate commerce, while in interstate commerce, or while held for sale after shipment in interstate commerce, as well as prohibiting the interstate transportation itself of adulterated or misbranded drugs. 21 U.S.C. § 331(a), (b), (k) and (c). Thus, these prohibitions reach the activities of "wholesalers, retailers, pharmacies, and hospitals, as well as manufacturers." *See* 55 FR 38020 at Comment 25 (specifically referencing scope of subsection (k) concerning drugs held for sale).

43. The FD&CA then defines that a drug is deemed adulterated if "the methods used in, or the facilities or controls used for, its manufacture, processing, **packing**, or holding do not conform to or are not operated or administered in conformity with **current good manufacturing practice** to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and **purity** characteristics, which it purports or is represented to possess." 21 U.S.C. § 351(a)(2)(B) (bold added).

44. The FD&CA also defines "misbranded" to include any labeling (broadly defined to include packaging, inserts, literature and all other forms of communication) that is false or misleading in any respect as to various factors, including safety and efficacy. 21 U.S.C. § 352; *see* 21 U.S.C. § 321(n)(requiring that a determination of misbranding because the labeling or

advertising is misleading shall take into account the failure to reveal facts material to consequences which may result from the use of the article).

45. The FD&CA also prohibits the introduction or delivery into interstate commerce of any article in violation of Section 355 governing FDA approval of new drugs. 21 U.S.C. § 331(d). That section includes not only approval of the indications for use, but also imposes conditions on the production, packing and handling of the drug product. In particular, that section requires that "the methods used in, and the facilities and controls used for, the manufacture, processing, and **packing** of such drug are []adequate to preserve its identity, strength, quality, and purity" and that the labeling is not "false or misleading in any particular." 21 U.S.C. § 355(d) and (e) (bold added).

46. Thus, the inclusion of these references to the concepts embodied in the more detailed prohibitions against adulteration and misbranding (e.g. Sections 351 and 352), make clear that, even though a drug formulation may have received "FDA-approval," the actual drug product is not in its FDA-approved form unless it complies with cGMP and proper labeling requirements. *U.S. v. Marcus*, 82 F.3d 606, 610 (4th Cir. 1996) (when drug product is adulterated and/or misbranded, the government "did not receive that which they bargained for – an FDA-approved drug of *known* safety and efficacy," and is entitled to recoup all sums paid for the drug) (italics in original); *U.S. v. Bhutani*, 266 F.3d 661, 670 (7th Cir. 2001).

47. The FD&CA also employs the same definition of "knowingly" or "knew" set forth in the False Claims Act, encompassing actual knowledge and deliberate ignorance or reckless disregard for the truth or falsity of information. 21 U.S.C. § 321(bb).

48. In 1978 the FDA promulgated regulations implementing the requirements, in 21 U.S.C. §§ 355(d) and (e) (FDA-approval) and 351(a)(2)(B) (adulteration), that drugs be handled

at all stages in conformity with current good manufacturing practices ("cGMP"). 21 C.F.R. Parts 210 and 211. The cGMP regulations expressly state that a drug is "adulterated" under 21 U.S.C. § 351(a)(2)(B) if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with cGMP regulations. 21 C.F.R. § 210.1(b).

49. In order for a drug to be considered "adulterated," it does not need to be shown that the drug is actually deficient as a result of the nonconformance. *See* 21 U.S.C. § 351(a). This is especially true with respect to any "reasonable possibility" of contamination with penicillin or other beta-lactams, where the regulatory duty to test in order to re-establish its safety clearly evinces a presumption of contamination and highlights the prophylactic nature of the adulteration prohibition. 21 C.F.R. § 211.176.

50. Penicillin is a type of beta-lactam antibiotic that is used in the treatment of bacterial infections. Due to the nature of penicillin, which induces allergic reactions in a significant portion of the population, the FDA has created special requirements for the manufacturing, processing and packaging of penicillin and other beta-lactam drugs. These requirements are included as part of the cGMP regulations, which are codified at 21 C.F.R. §§ 211-226, and specifically 21 C.F.R. § 211.42(c) and (d) and 21 C.F.R. § 211.176. According to the FDA's January 11, 2007 Warning Letter to Omnicare (discussed in further detail below), this prohibition includes all beta-lactam drugs.

51. Under cGMP regulations, **penicillin may not be packaged in the same facility where other non-penicillin drugs are packaged for human use**. 21 C.F.R. § 211.42(d). In addition, when the separate repackaging facility is within the same building where non-penicillin

products are packaged, then separate air-handling systems and other precautions must be implemented. *See* 21 C.F.R. § 211.42(c).

52. The cGMP regulations also require that all equipment shall be cleaned and, "as appropriate for the nature of the drug, sanitized and/or sterilized at appropriate intervals to prevent … contamination that would alter safety, strength, quality, or purity of the drug product beyond the official or other established requirements." 21 C.F.R. § 211.67.

53. Furthermore, when a "reasonable possibility existed that a non-penicillin drug product had been exposed to cross-contamination with penicillin," the non-penicillin drug is presumed to be contaminated and thus not in the form approved by the FDA for introduction into interstate commerce until such time as it has been tested to re-establish that it is safe to enter interstate commerce. 21 C.F.R. § 211.176.

54. Accordingly, non-penicillin drugs packed in the same building as penicillin drugs, sharing a common air re-circulating system, common entries and other employee spaces, and large open passageways between the two areas, have a "reasonable possibility" of being laced with penicillin, which induces an allergic reaction in up to two percent of patients. Thus, the drugs are "adulterated" and statutorily presumed to be unsafe and unfit for interstate commerce unless they are tested to re-establish their safety. Moreover, because the labeling fails to disclose this material risk, the drugs are also misbranded.

55. "Adulterated" and "misbranded" pharmaceuticals may not be introduced or delivered for introduction into interstate commerce. 21 U.S.C. §§ 331 and 355(d) and (e). Especially where, as here, the adulteration triggers a presumption that the drug product is no longer safe, and the testing required to re-establish its safety is not conducted, then the drug product does not qualify as FDA-approved and thus is ineligible for coverage under government

healthcare assistance and benefit programs. *Id.*; 42 U.S.C. §§ 1395y and 1396r-8(k)(2)(A)(i); and 42 C.F.R. § 423.100.

56. Because statutes expressly limit government coverage of drugs to those that meet all requirements and conditions of FDA-approval, it constitutes a False Claim for an entity to submit or cause to be submitted a claim for payment for a drug that was manufactured in violation of applicable statutes and regulations – including the FDA's cGMP regulations or the federal Food, Drug and Cosmetic Act.

Defendants' Business Operations

57. Defendants are engaged in the business of providing pharmacy services for patients/residents of long-term care facilities.

58. In 1994 Defendant Omnicare entered into a 50-50 partnership with Health Care Resources ("HCR"), n/k/a HCR Manor Care, to form Heartland Healthcare Services, an Ohio general partnership. Heartland Healthcare Services was located at 4755 South Avenue, Toledo, OH. From Omnicare's 10-K filings, it appears that from about 2000 through 2004 its general partnership interest was held by a wholly-named subsidiary, which is referenced herein as Doe Corporation 1.

59. Heartland Healthcare Services was comprised of several business units, including wholesaling & distribution, repackaging (high capacity, automated blister-packing), and a pharmacy. The operations were a vertically integrated system for purchasing, repackaging and reselling pharmaceuticals to Omnicare's and Heartland Healthcare Services' pharmacies which, in turn, dispensed them to residents at nursing homes owned by HCR.

60. In 2001, Omnicare bought out the wholesaling and repackaging units, and renamed them Heartland Repack Services, LLC, a 100% owned subsidiary formed in Delaware.

Since the typical statute of limitations under the FCA is six years, and since this action was filed in 2007, for ease of reference Relator refers to the repackaging operations as Heartland Repack.

61. Thereafter, Omnicare (or its wholly-owned subsidiary, Doe Corporation 1) and HCR continued to be 50-50 owners of Heartland Healthcare Services, which continued to operate the dispensing pharmacy in the building (serving Michigan and Ohio facilities) that Relator learned, in 2004, was frequently packaging penicillin and other beta-lactam drug products.

62. The building initially occupied by these business operations was previously used as a fur storage warehouse, and thus not originally designed for the uses to which Defendants put it. Heartland Healthcare Services moved into the facility in 1994, and at this time submitted plans for their business to the FDA for approval.

63. Based on information and belief, the facility proposal submitted by Heartland Healthcare Services detailed the floor layout plans for a long-term care pharmacy and a repackaging division within Heartland Healthcare Services. The proposal did not indicate that penicillin would be processed in the Heartland Healthcare Services repackaging division or the pharmacy division.

64. The FDA approved the plans and Heartland Healthcare Services' pharmacy began operating in 1994. In 1995 or 1996, the repackaging operations and wholesale & distribution units also began in the building. A few years later, the wholesale & distribution unit grew so large that part of it had to move to an off-site facility.

65. At all times since 1995 or 1996, the pharmacy unit was separated from the repackaging unit only by large overhead doors (similar to garage doors) which rolled open and shut. These doors were kept open approximately 25 percent of the time during business hours.

Inside the building, repackaging and pharmacy employees shared common break areas, entrances, and exits, and the same ventilation and heating/cooling system was used throughout the building.

66. As Relator later learned, at all times Heartland Healthcare Services' Toledo pharmacy manually repackaged penicillin and other beta-lactam drugs which were in two forms: pills and powder (for reconstituting into a liquid). Handling of both forms kicks-up beta-lactam dust into the ambient air.

67. One of Heartland Healthcare's parent companies, Defendant Omnicare, operated approximately 300 long-term care pharmacies which service SNFs and long-term care facilities in 47 states. Heartland Healthcare's other parent company, HCR operated a significant number of SNFs and long-term care facilities across the nation.

68. In 2001, Omnicare bought-out the wholesaling & distribution and repackaging units and named them Heartland Repack. At all times from 1995 or 1996 and thereafter until the repackaging operations were suspended in 2006 due, in part, to serious violations of cGMP, the repackaged drugs were sold at slightly above cost primarily to the 300 Omnicare pharmacies and the three Heartland Healthcare Services pharmacies (the other two were located in Florida). All of those pharmacies primarily served HCR-owned nursing homes caring for 1.4 million residents.

69. In 2000 Heartland Repack (then the repackaging division of Heartland Healthcare Services) purchased about 92 million doses at a cost of about $36 million (i.e. 2.5 cents per dose). By 2005 Heartland Repack had grown so much that it was repackaging over 200 million doses annually. A majority of the drugs repackaged by Heartland Repack were high-volume,

low-cost generics which had a high profit margin for the pharmacies. Over the years Heartland Repack also repackaged an increasing volume of brand drugs.

70. According to pp. 82-83 of Omnicare's March 16, 2006 10-K filing for the Securities and Exchange Commission ("SEC"), historically approximately one half of its revenue was derived "directly from government sources, principally state Medicaid programs and to a lesser extent the federal Medicare program." In 2005 Omnicare reported $5.3 billion in net sales revenue, with 46% "derived from beneficiaries covered under state Medicaid programs."

71. After Medicare Part D became effective on January 1, 2006, Omnicare's payor mix changed. According to its March 1, 2007 10-K filing, in 2006 Omnicare achieved $6.5 billion in net sales, with 42% from Medicare and 12% from Medicaid.

72. Initially, Heartland Repack was by far the largest of two repacking facilities owned and operated by Omnicare, the other being Vanguard. In later years, however, the two operations were about the same size. Thus, at all times Heartland Repack was the source for a majority of the drugs that generated Omnicare's revenue, including revenue from government programs and plans.

73. Most patients/residents of SNFs and other long-term care facilities require a variety of medications prescribed by their physicians.

74. Heartland Repack is designed to accommodate the residents at long-term care facilities by providing individually designed medication trays with doses of appropriate medications segregated into sealed cells or "blisters." This method of prepackaging allows medications to be dispensed by simply opening a "blister" at the designated medication time. For example, a SNF patient could have his morning dose of medication sealed in a "blister pack"

and ready for ingestion, rather than having to open a bottle or vial. Prepackaging is both convenient and adds a measure of safety.

75. As a business model, prepackaging created significant efficiencies and cost reductions for Omnicare. Prepackaging reduced the amount of manual pill counting and packaging done at its dispensing pharmacies, which now predominantly just pick the product off the rack and slap a patient label on it. In addition, prepackaging was increasingly automated which further reduced labor costs at the repacking facility. The biggest business driver, however, was the ever-higher rebate percentages that could be received from the drug manufacturers as Omnicare's automated repackaging increased the total volume of drugs they could handle.

76. At Heartland Repack, pills were purchased in bulk containers (sometimes barrels of 100,000 pills) and either sorted into "bingo cards" which is a 6-by-9 inch piece of plastic with the pill in a plastic bubble, or a "unit dose" which is smaller variety of bingo card.

77. The pharmaceutical distribution process began when Heartland Repack received an order for bingo cards or unit doses from an Omnicare pharmacy. Heartland Repack would process the order, and inscribe each bingo card or unit dose with a Lot Number, a Heartland Repack Services National Drug Code ("NDC") number[2], and the drug manufacturer's NDC number.

78. From there, the blister packs or other prepackaged drugs were shipped to Heartland Repack's Wholesale and Distribution Department (WDD). The WDD kept records of the drugs and lot numbers received.

[2] FDA regulations require registered drug establishments to provide the FDA with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. Drug products are identified and reported using a unique, three-segment number called the "NDC" number, which is a universal product identifier for human drugs.

79. The drugs were then sold at slightly above cost to Heartland Repack's wholesale & distribution unit which resold them at cost and shipped them to the three Heartland Healthcare Services pharmacies and the hundreds of Omnicare pharmacies across the nation, which in turn provided repackaged drugs to HCR Manor Care Nursing Homes and other long-term care facilities.

80. Specifically, HCR Manor Care Nursing Homes and other SNFs/ALFs would submit patient pharmaceutical orders to their regional Heartland Healthcare Services or Omnicare pharmacy for processing. The orders would then be processed by the pharmacy intake department (which verifies all patient payor sources such as Medicare, Medicaid, private insurance, etc.), packed into a plastic "tote bag" for each patient, and shipped to the appropriate care facility.

81. Each nursing facility received Medicare payments for each Part A beneficiary and paid Omnicare or Heartland Healthcare Services pharmacies for drugs based upon a previously-negotiated agreement between the pharmacy and the facility. Each nursing facility then reported the price it paid for the drugs as "allowable costs" in its annual Medicare Cost Report. Because Defendants caused the drugs to be adulterated and misbranded and therefore not in their FDA-approved form, especially as to safety requirements, the drugs were ineligible for coverage. Thus, Defendants' conduct rendering the drugs ineligible for coverage concomitantly rendered the SNFs' Medicare Part A Cost Reports false or fraudulent.

82. For patients at ALFs or SNFs that were covered under MA or MA-PD plans, coverage of their drugs would have depended on whether they were effectively being covered under Medicare Part A or Part D. In either event, the Defendant pharmacies billed the Medicare Part C Providers who in turn received funds from the government. To the extent the law

required the Part C Providers to provide the government with pricing and other data concerning these prescriptions to ensure that Medicare ultimately only paid for the actual cost of FDA-approved drugs dispensed, then Defendants' conduct rendering the drugs ineligible for payment concomitantly rendered the data submitted to justify their coverage false and/or fraudulent.

83. Beginning January 1, 2006, drug claims for Medicare Part D patients at ALFs or SNFs were billed to Medicare Part D Providers ("PDP") directly by Omnicare pharmacies which were reimbursed in accordance with agreements previously negotiated with the PDP or the PBM it contracted with to administer the plan. As required by law, pricing and other data concerning each individual prescription was then submitted by the PDP to Medicare to be used as part of the year-end reconciliation process designed to ensure that Medicare ultimately only pays for the actual cost of FDA-approved drugs dispensed. Defendants' conduct rendering the drugs ineligible for payment concomitantly rendered the data submitted to justify their coverage false and/or fraudulent.

84. State Medicaid programs were also billed directly by the Omnicare and Heartland Healthcare Services pharmacies for drugs provided to Medicaid beneficiaries, and the Omnicare and Heartland Healthcare Services pharmacies were paid directly by each state's Medicaid agency in accordance with that state's Medicaid reimbursement formulas. Defendants' conduct rendering the drugs ineligible for payment concomitantly rendered the claims for direct payment false and/or fraudulent.

Defendants' Fraudulent Activities

85. During Relator's tenure as Senior Director of Operations, Heartland Repack employed over 100 individuals on a regular basis. The repackaging operation provided repackaged pharmaceuticals to all of the Omnicare pharmacies.

86. Omnicare is one of the country's largest providers of pharmaceutical care for senior citizens – during an average month, Relator's repackaging unit packaged approximately 1.3 million bingo cards and 20 million unit doses.

87. One of Omnicare's top executives, and Relator's direct supervisor, was Denis Holmes, Sr. Vice President of Omnicare, Inc. Mr. Holmes was responsible for key operations in the Omnicare Senior Pharmacy Services Division, including repacking and wholesale operations.

88. Holmes was also responsible for the relationship with Omnicare's largest single customer, HCR, with whom it operated a joint venture pharmacy, namely the Heartland Healthcare Services pharmacy. Holmes was one of the three Omnicare executives that served on the Heartland Healthcare Services management committee. Holmes had been responsible for all of the business units at the Toledo building since the inception of the project in 1994, and thus was intimately familiar with all operations taking place there.

89. Holmes was also responsible for pricing, including Medicare and managed care, and was responsible for the administration of the annual management meeting at which Omnicare management discussed and planned its annual operational goals and objectives, sales and marketing strategies, and the tactics to achieve those goals.

90. During a Heartland Repack monthly meeting in mid-2004, Holmes suggested that Relator add amoxicillin and penicillin to the list of drugs that Relator's department repackaged as a way to increase profits.

91. Relator informed Holmes during the meeting that as an FDA-licensed repackaging facility, Heartland Repack could not repackage penicillin-based drugs alongside other drugs, as doing so would violate FDA guidelines.

92. Holmes was skeptical of Relator's assertion, and asked that Relator provide him with copies of the applicable regulations prohibiting the repackaging of penicillin alongside non-penicillin-based pharmaceuticals. Holmes also requested that Relator confer with Ralph Breitfeller, Omnicare's attorney.

93. Relator researched the matter and recorded his findings in a memorandum, which he emailed to Denis Holmes and copied Ralph Breitfeller on. His research confirmed his assertion during the meeting that repackaging penicillin alongside the other pharmaceuticals was in fact in violation of FDA regulations. The memo contained citations from the appropriate cGMP guidelines, as well as references to specific cases where the FDA fined and shut down facilities that were in violation of the regulations.

94. While researching FDA guidelines, Relator contacted Sharon Bombrys, who was the pharmacy manager for the adjacent Heartland Healthcare Services pharmacy. Bombrys informed Relator that the Heartland Healthcare pharmacy repacked penicillin frequently, and added that as a pharmacy it was allowed to do so under applicable state of Ohio Board of Pharmacy laws.

95. Regardless of the Ohio Board of Pharmacy's role, Heartland Healthcare Services' Toledo pharmacy was still subject to the FD&CA laws against adulteration and misbranding, and the FDA cGMP regulations – including those governing the handling of penicillin and other beta-lactam drugs. 21 U.S.C. § 331(k); *see* 55 FR 38020 at Comment 25. Hence, all non-penicillin products repackaged and dispensed by Heartland Healthcare Services' Toledo pharmacy were also adulterated and misbranded in such a manner that they were not in their FDA-approved form and thus ineligible for coverage under government health care assistance programs and benefit plans.

96. Prior to his conversation with Bombrys, Relator was not aware that penicillin was being repackaged at the Heartland Healthcare pharmacy.

97. After emailing the memorandum to Denis Holmes and Ralph Breitfeller, Relator met with Denis Holmes one evening in a conference room. Relator mentioned to Holmes that he had spoken with Bombrys, who informed him the Heartland Healthcare Services pharmacy repackaged penicillin. Holmes requested that Relator call Ralph Breitfeller and discuss the issue.

98. Relator called Ralph Breitfeller the next day to discuss the memorandum and his findings.

99. During the telephone conversation, Breitfeller agreed with Relator's conclusions to the extent that Heartland Repack could not legally repackage penicillin.

100. However, when Relator mentioned that Heartland Healthcare Services' pharmacy was repackaging penicillin in the same building as Heartland Repack, and this could also be a problem, Breitfeller disagreed. Breitfeller stated that the FDA had reviewed the floor plans for the plant layout and had not found fault with them.

101. Relator responded that simply because the FDA did not find any faults with the Heartland Healthcare Services floor plan when originally presented for approval in 1994, this did not mean that the current 2004 wholesale repackaging operations (i.e. Heartland Repack) were in compliance with FDA regulations.

102. Relator then contacted Holmes to share his findings and discuss his conversation with Ralph Breitfeller.

103. Holmes directed Relator to research methods in which Heartland Repack could legally repackage penicillin. During this conversation, Relator also mentioned that he had

discovered the Heartland Healthcare Services pharmacy was repackaging penicillin and that this could be a major problem.

104. Holmes asked Relator if he had shared his finding about Heartland Healthcare Services pharmacy's repackaging practices with Breitfeller. Relator stated that he had, and Breitfeller had said he did not think it was a problem; however, Relator also emphatically stated that he disagreed with Breitfeller's conclusion.

105. Pursuant to Holmes' instructions, Relator researched different methods in which Heartland Repack could legally repackage penicillin and determined there were three methods of doing so: 1) to locate a different packager and subcontract the work out; 2) conduct the repackaging in an off-site facility; and 3) isolate the proposed penicillin repacking within Heartland Repack's portion of the building (i.e. create a separate entrance and exit where its employees could not co-mingle with other Heartland Repack employees, and provide separate ventilation and air handling systems). Relator also calculated the approximate costs for implementing suggestions 2 and 3. The estimated cost for constructing option 3, the "clean room," was $250,000 - $500,000.

106. Relator stopped by Holmes' office and shared the above conclusions and the estimated costs for doing so. During this encounter, Relator again voiced his concern over the fact that Heartland Healthcare Services' pharmacy was repacking penicillin in the same facility as Heartland Repack.

107. Holmes responded to Relator's concerns about Heartland Healthcare Services by stating that "Ralph [Breitfeller] said it wasn't a problem." In short, Omnicare – by and through its corporate executives Denis Holmes and Ralph Breitfeller – exercised control over Heartland Repack and denied Relator the authority to bring Heartland Repack into compliance with

FD&CA laws and FDA regulations designed to ensure that drugs were not cross-contaminated with penicillin and other beta-lactam products.

108. Holmes did not respond to Relator's suggestions regarding legal methods in which Heartland Repack could repackage penicillin. After Relator left Holmes' office, the issue of repackaging penicillin at Heartland Repack was not brought up again.

109. On or about February 28, 2006, Relator resigned from Heartland Repack after repeated disagreements with management over quality control policies. In addition to the foregoing cross-contamination issue, Heartland Repack was expanding rapidly and thus it was necessary to hire additional employees to monitor quality control. Omnicare, however, denied Heartland Repack the authority to do so.

110. Approximately four or five months after resigning from Heartland Repack, Relator was hired as a consultant with a pharmaceutical benefits management company. While traveling on business, Relator landed at the Cleveland Hopkins airport in Ohio and used a pay phone to call the FDA Unit in Cincinnati and report Heartland Repack's improper repackaging practices.

111. Under applicable guidelines, the FDA regulated Heartland Repack while the Heartland Healthcare pharmacy was regulated in the first instance by the State of Ohio. Acting on Relator's tip, FDA inspectors visited Heartland Repack to determine if penicillin was being repackaged alongside other drugs. Employees in the repackaging unit responded that "no penicillin was being repackaged in the Repackaging Division" – a statement that was misleading because it failed to disclose that penicillin was being repacked in the pharmacy located in the same building, with a common air-handling system, common doorways and other facilities. Hearing this response, the FDA representatives left the premises.

112. Thereafter, Relator made an appointment to speak with agents at the FDA in an attempt to correct the misleading report, and to assist the agents in the investigation he initiated.

113. Relator was interviewed by two FDA agents, Matthew Casale and Robert Rodriguez, in Toledo, Ohio. He described the specific details of the penicillin exposure at Heartland Repack's Toledo facility.

114. The FDA, in collaboration with the State of Ohio, inspected the Heartland Healthcare Services pharmacy and verified that penicillin was, in fact, being repackaged in the same building as Heartland Repack. This was in violation of FDA guidelines and regulations. Additional testing was performed which revealed the presence of penicillin throughout the building. The presence of beta-lactam residue in Heartland Repack's part of the building was also shown by Omnicare's own tests, as admitted by Omnicare in its 2006 10-K at pp. 54 and 139, and subsequent SEC filings.

115. On or about January 11, 2007, the FDA issued a Warning Letter to Joel F. Germunder, President and CEO of Omnicare, concerning the results of the FDA inspection conducted at Heartland Repack from June 27, 2006 through August 11, 2006. (*See* **Exhibit 1**).

116. The above inspection and audit were caused and precipitated by Relator, who originally brought Heartland Repack's unlawful activities to the attention of the FDA.

117. Page 7 of the FDA Warning Letter acknowledges receipt of Omnicare's August 28, 2006 response to the FDA-483 Inspectional Observations. It then recounts Omnicare's commitment to corrective actions, including: ceasing all production of all products on July 27, 2006 and placing all products in quarantine that are under Heartland Repack's control; initiating a penicillin sampling program with environmental swabs and product testing, and ceasing all distribution of products until testing is complete; permanently moving the drug repackaging

operation to a new facility; and evaluating all equipment for decontamination procedures and if not feasible replacing the equipment.

118. It follows that the Heartland Healthcare Services pharmacy in the building was at least as contaminated with beta-lactam residue, and probably more so, since that is the location in the building where the beta-lactam repackaging occurred. Hence, the non-penicillin drugs in that facility were equally or more subject to a "reasonable possibility" of contamination rendering them adulterated, misbranded, unfit for interstate commerce and ineligible for coverage under government healthcare plans and programs, unless and until they were tested to re-establish their safety.

119. Based upon information and belief, Omnicare and/or Heartland Repack conducted the environmental tests set forth in Omnicare's July 27, 2006 commitment to the FDA. Those tests found beta-lactam residue on every horizontal surface in Heartland Repack. Omnicare briefly mentioned its testing and the presence of beta-lactam residue in its 2006 10-K filing.

120. Based upon information and belief, neither Omnicare nor Heartland Repack ever conducted any product testing as set forth in Omnicare's July 27, 2006 commitment to the FDA. Such testing was intended to determine the actual level of beta-lactam residue on those drugs in order to overcome the statutory presumption of contamination and clear the drugs for introduction into interstate commerce pursuant to 42 C.F.R. § 211.176. Instead, and as apparent from Omnicare's 2006 10-K filing at p. 54, Defendants simply wrote-off the inventory at a pretax cost of $18.9 million and disposed of the drugs. In so doing, Omnicare and Heartland Repack prevented the creation of any scientific evidence of the actual level of beta-lactam contamination on that inventory and spoliated the raw evidence itself.

121. Based on information obtained from the FDA Enforcement Reports (www.fda.gov/opacom/Enforce.html) Defendants have not recalled any pharmaceuticals due to penicillin contamination. Based on information and belief, Defendants have not reimbursed the federal or state governments for any monies the governments improperly paid to Defendants or others for the adulterated, misbranded and ineligible pharmaceuticals.

122. In sum, through their vertically integrated companies, Defendants purchased drugs which they then, with actual knowledge or deliberate ignorance or reckless disregard for the truth, repackaged the drugs in manners that did not comply with cGMP designed to guard against cross-contamination from penicillin and other beta-lactam drugs. This which triggered the statutory presumption that the drugs were unsafe, and thus adulterated and misbranded, unless and until tested to re-establish their safety. Because such testing was never conducted, the drugs remained adulterated and misbranded, and thus not in their FDA-approved form. As such, according to statutes and regulations defining government coverage for drugs, the drug products were ineligible for payment under any government healthcare assistance program or benefit plan.

123. Notwithstanding the foregoing, Defendants then distributed the non-FDA-approved drug products to their own pharmacies, which then sold them to its beta-lactam mishandling partner, HCR Manor Care, which then administered them to many of its 1.4 million unsuspecting nursing home residents.

124. As to residents covered under Medicare Part A, the HCR Manor Care nursing homes submitted annual Cost Reports to Medicare Part A listing the drugs as allowable costs. Defendants' conduct rendering the drugs ineligible for government payment, reinforced by its involvement in the distribution process, concomitantly rendered and caused the ensuing Medicare Part A Cost Reports false or fraudulent.

125. As to residents whose drugs were covered under Medicare Part D, Defendants' pharmacies themselves billed the Providers for the non-FDA-approved drugs and provided said Providers with prescription drug event data that was forwarded to Medicare to justify and reconcile receipt of government funds. Defendants' conduct rendering the drugs ineligible for government payment, reinforced by its involvement in the distribution and claims process, concomitantly rendered and caused the ensuing Medicare Part D data submissions false or fraudulent.

126. As to residents whose drugs were covered under Medicaid, Defendants' pharmacies themselves directly billed and received payment from state Medicaid agencies across the country. Defendants' conduct rendering the drugs ineligible for government payment rendered and caused the ensuing Medicaid claims to be false or fraudulent. More directly, Defendants' pharmacies themselves submitted the false or fraudulent claims to Medicaid.

127. In short, since the pharmaceuticals were contaminated with penicillin and distributed in violation of federal laws and regulations that rendered them not in their FDA-approved form, the drugs were ineligible for coverage under government-funded health care assistance programs and benefit plans. Thus, Defendants' actions of Omnicare pharmacies in submitting reimbursement claims for such pharmaceuticals, or causing reimbursement claims to be submitted, constituted false claims.

Equitable Tolling

128. Defendants' conduct, as alleged herein, was, upon information and belief, purposeful and deliberately fraudulent and misleading, with the intent and effect of affirmatively representing and/or implying that they were complying in good faith with applicable laws, while omitting, hiding, and/or otherwise concealing the acts and practices complained of herein on an

ongoing, continuous, and repeated basis, which equitably tolled or otherwise suspended the running of any and all applicable statutes of limitations.

COUNT I

False Claims Act - Presentation of False Claims

129. Relator re-alleges and incorporates paragraphs 1-128 of this Complaint as if fully set forth herein.

130. In performing the acts described above, Defendants through their own acts or through the acts of their officers, knowingly presented, or caused to be presented, to an officer or employee of the United States government, false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1).

131. Specifically, Defendants Omnicare and Heartland Repack knowingly and/or recklessly repackaged drugs at Heartland Repack in violation of applicable laws, including cGMP, which rendered them presumptively unsafe under cGMP regulations, and therefore adulterated and misbranded, and therefore not in their FDA-approved form, and thus ineligible for coverage under government programs.

132. In addition, Defendant Omnicare and/or Doe Corporation 1, as the general partner of Heartland Healthcare Services, knowingly repackaged penicillin in its Toledo pharmacy in a manner that was not in compliance with applicable laws including cGMP, knowing that it was doing so in the same building as Heartland Repack which it knew to be repackaging non-penicillin drugs. As such, Omnicare and/or Doe Corporation 1 rendered the non-penicillin drugs repackaged by Heartland Repack presumptively unsafe under cGMP regulations, and therefore adulterated and misbranded, and therefore not in their FDA-approved form, and thus ineligible for coverage under government programs.

133. In further addition, Defendant Omnicare and/or Doe Corporation 1, as a general partner of Heartland Healthcare Services, knowingly repackaged penicillin in its Toledo pharmacy in a manner that that was not in compliance with applicable laws including cGMP, knowing that it was doing so in the same pharmacy facility in which it was itself handling non-penicillin drugs. As such, Omnicare and/or Doe Corporation 1 rendered the non-penicillin drugs that it handled presumptively unsafe under cGMP regulations, and therefore adulterated and misbranded, and therefore not in their FDA-approved form, and thus ineligible for coverage under government programs.

134. In all instances described in the foregoing three paragraphs, Defendants Omnicare, Doe Corporation 1, and/or Heartland Repack supplied the adulterated and misbranded non-penicillin drugs to Omnicare and/or Heartland Healthcare Services pharmacies for dispensing to patients and billing to government payors. Hence, as to such drugs, Defendants caused to be false or fraudulent the presentment of: all claims to Medicaid; all prescription drug event data and other reconciliation data submitted to Medicare by Part D Providers; all claims, cost reports, prescription drug event data or other data submitted to Medicare in connection with Part C coverage; and all Medicare Part A Cost Reports submitted by SNFs and ALFs listing payment for such drugs as an allowable cost.

135. Furthermore, Defendants Omnicare, Doe Corporation 1 and/or Heartland Repack, either directly or through Omnicare and/or Heartland Healthcare Services pharmacies, which are all enrolled as Medicare and Medicaid providers, presented or caused to be presented claims which falsely implied certification of compliance with all conditions of payment under those programs, including compliance with relevant federal statutes and regulations – and specifically

including those defining covered drugs as only those in FDA-approved form including compliance with cGMP and the prohibitions against adulteration and misbranding.

136. The United States, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

COUNT II

False Claims Act - False Statements

137. Relator re-alleges and incorporates paragraphs 1-136 of this Complaint as if fully set forth herein.

138. In performing the acts described above, Defendants through their own acts or through the acts of their officers, knowingly made, used, or caused to be made or used, a false record or statement to get false or fraudulent claims paid or approved by the government in violation of 31 U.S.C. § 3729(a)(2).

139. The United States, unaware of the foregoing circumstances and conduct of the Defendants, made full payments which resulted in its being damaged in an amount to be determined.

COUNT III

False Claims Act – Reverse False Claims

140. Relator re-alleges and incorporates paragraphs 1-139 of this Complaint as if fully set forth herein.

141. In performing the acts described above, Defendants knowingly made, used, or caused to be made or used, false records and statements to conceal the obligation to return to the

federal Government monies improperly obtained and retained, in violation of 31 U.S.C. § 3739(a)(7).

142. Through Defendants' actions of improperly retaining funds to which they are not entitled, the United States has been deprived of the use of these monies and is entitled to damages in an amount to be determined.

COUNT IV

California False Claims Act - Cal. Govt. Code §§ 12650 *et seq*.

143. Relator re-alleges and incorporates paragraphs 1-142 of the Complaint as if fully set forth herein.

144. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives, knowingly presented or caused to be presented to the California state government fraudulent claims for payment in violation of Cal. Govt. Code § 12651(a)(1).

145. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly made or caused to be made or used a false record or statement to get a false claim paid or approved by the California state government in violation of Cal. Govt. Code § 12651(a)(2).

146. The State of California, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

147. The State of California is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT V

Delaware False Claims and Reporting Act - 6 Del. C. §§ 1201 *et seq*.

148. Relator re-alleges and incorporates paragraphs 1-147 of the Complaint as if fully set forth herein.

149. In performing the acts described above, Defendants, through the acts of their officers, knowingly presented or caused to be presented to the Delaware State Government fraudulent claims for payment in violation of 6 Del. C. § 1201(a)(1).

150. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly made or caused to be made or used a false record or statement to get a false claim paid or approved by the Delaware state government in violation of 6 Del. C. § 1201 (a)(2).

151. The State of Delaware, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

152. The State of Delaware is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT VI

District of Columbia False Claims Act - D.C. Ann. §§ 2-308.03 *et seq*.

153. Relator re-alleges and incorporates paragraphs 1-152 of the Complaint as if fully set forth herein.

154. In performing the acts described above, Defendants, through the acts of their officers, knowingly presented or caused to be presented to the District of Columbia government fraudulent claims for payment in violation of D.C. Ann. § 2-38.14(a)(1).

155. In performing the acts described above, Defendants, through the acts of their officers, knowingly made or caused to be made or used a false record or statement to get a false claim paid or approved by the District of Columbia government in violation of D.C. Ann. § 2-38.14(a)(2).

156. The District of Columbia, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

157. The District of Columbia is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT VII

Florida False Claims Act - Fla. Stat. Ann. §§ 68.081 *et seq*.

158. Relator re-alleges and incorporates paragraphs 1-157 of the Complaint as if fully set forth herein.

159. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to the Florida state government fraudulent claims for payment in violation of Fla. Stat. Ann. § 68.082(2)(a).

160. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly made or caused to be made or

used a false record or statement to get a false claim paid or approved by the Florida state government in violation of Fla. Stat. Ann. § 68.082(2)(b).

161. The State of Florida, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

162. The State of Florida is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT VIII

Georgia State False Medicaid Claims Act – Ga. Code Ann. §§ 49-4-168 *et seq*.

163. Relator re-alleges and reincorporates paragraphs 1-162 of this Complaint as if fully set forth herein.

164. In performing the acts described above, Defendant, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to the Georgia state government fraudulent claims for payment in violation of the Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.1(a)(1).

165. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly made or caused to be made or used a false record or statement to get a false claim paid or approved by the Georgia state government in violation of Georgia's State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.1(a)(2).

166. The State of Georgia, unaware of the foregoing circumstances and conduct of the Defendants, made full payments which resulted in its being damages in an amount to be determined.

167. The State of Georgia is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by the Defendants.

COUNT IX

Hawaii False Claims Act - Haw. Rev. Stat. §§ 661-21 et seq.

168. Relator re-alleges and incorporates paragraphs 1-167 of the Complaint as if fully set forth herein.

169. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to the Hawaii state government fraudulent claims for payment in violation of Haw. Rev. Stat. § 651-21(a)(1).

170. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly made or caused to be made or used a false record or statement to get a false claim paid or approved by the Hawaii state government in violation of Haw. Rev. Stat. § 651-21(a)(2).

171. The State of Hawaii, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

172. The State of Hawaii is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT X

Illinois Whistleblower Reward and Protection Act - 740 Ill. Comp. Stat. §§ 175/1 *et seq*.

173. Relator re-alleges and incorporates paragraphs 1-172 of the Complaint as if fully set forth herein.

174. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to the Illinois state government fraudulent claims for payment in violation of 740 Ill. Comp. Stat. § 175/3(a)(1).

175. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly made or caused to be made or used a false record or statement to get a false claim paid or approved by the Illinois state government in violation of 740 Ill. Comp. Stat. § 175/3(a)(2).

176. The State of Illinois, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

177. The State of Illinois is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT XI

Indiana False Claims and Whistleblower Protection Act – Ind. Code §§ 5-11-5.5-1 *et seq*.

178. Relator re-alleges and incorporates paragraphs 1-177 of the Complaint as if fully set forth herein.

179. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented to the Indiana state government fraudulent claims for payment in violation of the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-2(b)(1).

180. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly made or used a false record or statement to get a false claim paid or approved by the Indiana government in violation of the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-1(b)(2).

181. The State of Indiana, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

182. The State of Indiana is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT XII

Louisiana Medical Assistance Programs Integrity Law,

La. Rev. Stat. Ann. §§ 46:437.1 *et seq*.

183. Relator re-alleges and incorporates paragraphs 1-182 of the Complaint as if fully set forth herein.

184. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives, knowingly presented or caused to be presented to the Louisiana state government false or fraudulent claims for payment in violation of Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:438.3(A).

185. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly submitted a claim for goods, services or supplies which were medically unnecessary or which were of substandard quality and quantity to the Louisiana state government in violation of the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:438.3(E)(1).

186. The State of Louisiana, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

187. The State of Louisiana is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT XIII

Massachusetts False Claims Law - Mass. Gen. Laws Ch. 12 §§ 5A *et seq*.

188. Relator re-alleges and incorporates paragraphs 1-188 of the Complaint as if fully set forth herein.

189. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to the Massachusetts state government fraudulent claims for payment in violation of Mass Gen. Laws Ch. 12 § 5B(1).

190. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly made or caused to be made or used a false record or statement to get a false claim paid or approved by the Massachusetts state government in violation of Mass. Gen. Laws Ch. 12 § 5B(2).

191. The State of Massachusetts, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

192. The State of Massachusetts is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT XIV

Michigan Medicaid False Claims Act, Mich. Comp. Laws §§ 400.601 *et seq*.

193. Relator re-alleges and incorporates paragraphs 1-192 of the Complaint as if fully set forth herein.

194. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to the Michigan state government fraudulent claims for payment in violation of Mich. Comp. Laws § 400.607(1).

195. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly made or presented, or caused to be made and presented, a claim for Medicaid benefits which were known to falsely represent that the goods or services for which the claim is made were medically necessary in accordance with professionally accepted standards in violation Mich. Comp. Laws § 400.607(2).

196. The State of Michigan, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

197. The State of Michigan is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT XV

Montana False Claims Act - Mon. Stat. §§ 17-8-401 *et seq.*

198. Relator re-alleges and incorporates paragraphs 1-197 of the Complaint as if fully set forth herein.

199. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to the Montana state government fraudulent claims for payment in violation of Mon. Stat. § 17-8-403(1)(a).

200. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly made or caused to be made or used a false record or statement to get a false claim paid or approved by the Montana state government in violation of Mon. Stat. § 17-8-403(1)(b).

201. The State of Montana, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

202. The State of Montana is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT XVI

Nevada False Claims Act - Nev. Rev. Stat. §§ 357.020 *et seq*.

203. Relator re-alleges and incorporates paragraphs 1-202 of the Complaint as if fully set forth herein.

204. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to the Nevada state government fraudulent claims for payment in violation of Nev. Rev. Stat. § 357.040(1)(a).

205. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly made or caused to be made or used a false record or statement to get a false claim paid or approved by the Nevada State Government in violation of Nev. Rev. Stat. § 357.040(1)(b).

206. The State of Nevada, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

207. The State of Nevada is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT XVII

New Hampshire False Claims Act – N.H. Rev. Stat. Ann. §§ 167: 61-b *et seq.*

208. Relator re-alleges and incorporates paragraphs 1-207 of the Complaint as if fully set forth herein.

209. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to the New Hampshire state government fraudulent claims for payment in violation of N.H. Rev. Stat. Ann. § 167: 61-b(I)(a).

210. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly made or caused to be made or used a false record or statement to get a false claim paid or approved by the New Hampshire state government in violation of N.H. Rev. Stat. Ann. § 167: 61-b(I)(b).

211. The State of New Hampshire, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

212. The State of New Hampshire is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT XVIII

New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 *et seq.*

213. Relator re-alleges and incorporates paragraphs 1-212 of the Complaint as if fully set forth herein.

214. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to the New Jersey state government fraudulent claims for payment in violation of the New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-3(a).

215. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly made or caused to be made or used a false record or statement to get a false claim paid or approved by the New Jersey government in violation of the New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-3(b).

216. The State of New Jersey, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

217. The State of New Jersey is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT XIX

New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 *et seq*.

218. Relator re-alleges and incorporates paragraphs 1-217 of the Complaint as if fully set forth herein.

219. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to the State of New Mexico fraudulent claims for payment under the Medicaid program in violation of the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-4(A).

220. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly made or caused to be made or used a false record or statement to get a false claim under the Medicaid program paid or approved by State of New Mexico in violation of the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-4(C).

221. The State of New Mexico, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

222. The State of New Mexico is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT XIX

New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 *et seq*.

223. Relator re-alleges and incorporates paragraphs 1-222 of the Complaint as if fully set forth herein.

224. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to the State of New Mexico false or fraudulent claims for payment or approval in violation of the New Mexico Medicaid False Claims Act ("NMFATA"), N.M. Stat. Ann. § 44-9-3A(1).

225. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly made or used, or caused to be

made or used, a false, misleading or fraudulent record or statement to get a false claim paid or approved by the State of New Mexico in violation of NMFATA, N.M. Stat. Ann. § 44-9-3A(2).

226. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly made or used, or caused to be made or used, a false, misleading or fraudulent record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the State of New Mexico in violation of NMFATA, N.M. Stat. Ann. § 44-9-3A(8).

227. The State of New Mexico, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

228. The State of New Mexico is entitled to treble damages and civil recoveries for each and every false, misleading or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants. N.M. Stat. Ann. § 44-9-3C.

229. NMFATA was enacted July 1, 2007, but is expressly retroactive and reaches back to any misconduct occurring on or after July 1, 1987. N.M. Stat. Ann. § 44-9-12.

COUNT XX

New York False Claims Act, N.Y. Finance Law §§ 187 *et seq*.

230. Relator re-alleges and incorporates paragraphs 1-229 of the Complaint as if fully set forth herein.

231. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to the New York state government fraudulent claims for payment or approval in violation of the New York False Claims Act, N.Y. Finance Law § 189(a).

232. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly made or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the New York state government in violation of the New York False Claims Act, N.Y. Finance Law § 187(b).

233. The State of New York, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

234. The State of New York is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT XXI

Oklahoma Medicaid False Claims Act – 63 Ok. Stat. Ann. §§ 5053 *et seq*.

235. Relator re-alleges and incorporates paragraphs 1-234 of the Complaint as if fully set forth herein.

236. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to the Oklahoma state government false or fraudulent claims for payment or approval in violation of 63 Ok. Stat. Ann. § 5053.1(B)(1).

237. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Oklahoma state government in violation of 63 Ok. Stat. Ann. § 5053.1(B)(2).

238. The State of Oklahoma, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

239. The State of Oklahoma is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT XXII

Rhode Island State False Claims Act, R.I. Gen. Laws §§ 9-1.1-1 *et seq*.

240. Relator re-alleges and incorporates paragraphs 1-239 of the Complaint as if fully set forth herein.

241. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to the Rhode Island state government fraudulent claims for payment in violation of the Rhode Island State False Claims Act, R.I. Gen. Laws § 9-1.1-3(a)(1).

242. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Rhode Island government in violation of the Rhode Island State False Claims Act, R.I. Gen. Laws § 9-1.1-3(a)(2).

243. The State of Rhode Island, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

244. The State of Rhode Island is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT XXIII

Tennessee Medicaid False Claims Act - Tenn. Code. Ann. §§ 71-5-181 *et seq*.

245. Relator re-alleges and incorporates paragraphs 1-244 of the Complaint as if fully set forth herein.

246. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to the Tennessee state government a false or fraudulent claims under the Medicaid program in violation of the Tennessee Medicaid False Claims Act, Tenn. Code. Ann. § 71-5-182(a)(1)(A).

247. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim under the Medicaid program paid or approved by the Tennessee state government in violation of the Tennessee Medicaid False Claims Act Tenn. Code Ann. § 71-5-182 (a)(1)(B).

248. The State of Tennessee, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

249. The State of Tennessee is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT XXIV

Texas False Claims Act - Tx. Hum. Res. Code Ann. §§ 32.039 *et seq*. and §§ 36.002 *et seq*.

250. Relator re-alleges and incorporates paragraphs 1-249 of the Complaint as if fully set forth herein.

251. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to the Texas state government fraudulent claims for payment in violation of Tx. Hum. Res. Code. Ann. §§ 32.039 and §§ 36.002 *et seq*.

252. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly made or caused to be made or used a false record or statement to get a false claim paid or approved by the Texas state government in violation of Tx. Hum. Res. Code Ann. §§ 32.039 and §§ 36.002 *et seq*.

253. The State of Texas, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

254. The State of Texas is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT XXV

Virginia Fraud Against Taxpayers Act - Va. Code Ann. §§ 8.01-216.1 *et seq*.

255. Relator re-alleges and incorporates paragraphs 1-254 of the Complaint as if fully set forth herein.

256. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to the Virginia state government fraudulent claims for payment or approval in violation of Va. Code Ann. §8.01-216.3(A)(1).

257. In performing the acts described above, Defendants, through the acts their officers, agents, employees and sales representatives, knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Virginia state government in violation of Va. Code Ann. § 8.01-216.3(a)(2).

258. The State of Virginia, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

259. The State of Virginia is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT XXVI

Wisconsin False Claims for Medical Assistance Act, Wis. Stat. §§ 20.931 *et seq*.

260. Relator re-alleges and incorporates paragraphs 1-259 of the Complaint as if fully set forth herein.

261. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to the Wisconsin state government fraudulent claims for payment in violation of the Wisconsin False Claims for Medical Assistance Act, Wis. Stat. §§ 20.931(2)(a).

262. In performing the acts described above, Defendants, through the acts their officers, agents, employees and sales representatives, knowingly made or caused to be made or used a false record or statement to get a false claim paid or approved by the Wisconsin state government in violation of the Wisconsin False Claims for Medical Assistance Act, Wis. Stat. §§ 20.931(2)(b).

263. The State of Wisconsin, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

264. The State of Wisconsin is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT XXVII

City of Chicago False Claims Act §§ 1-22-010 *et seq*.

265. Relator re-alleges and incorporates paragraphs 1-264 of the Complaint as if fully set forth herein.

266. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to the City of Chicago fraudulent claims for payment in violation of the Chicago False Claims Act § 1-22-010.

267. In performing the acts described above, Defendants, through the acts their officers, agents, employees and sales representatives, knowingly made or caused to be made or used a false record or statement to get a false claim paid or approved by the City of Chicago in violation of Chicago False Claims Act § 1-22-010.

268. The City of Chicago, unaware of the foregoing circumstances and conduct of the Defendants, made full payments which resulted in its being damaged in an amount to be determined.

269. The City of Chicago is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT XXVIII

New York City False Claims Act Local Law 53 of 2005, §§ 7-801 *et seq*.

270. Relator re-alleges and incorporates paragraphs 1-269 of the Complaint as if fully set forth herein.

271. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to the City of New York fraudulent claims for payment in violation of the New York False Claims Act, Local Law 53 of 2005, § 7-803(1).

272. In performing the acts described above, Defendants, through the acts their officers, agents, employees and sales representatives, knowingly made or caused to be made or used a false record or statement to get a false claim paid or approved by the City of New York in violation of the New York False Claims Act Local Law 53 of 2005, § 7-803(2).

273. The City of New York, unaware of the foregoing circumstances and conduct of the Defendants, made full payments which resulted in its being damaged in an amount to be determined.

274. The City of New York is entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

COUNT XXIX

Cook County False Claims Act, Resolution No. 03-R-394

275. Relator re-alleges and incorporates paragraphs 1-274 of the Complaint as if fully set forth herein.

276. In performing the acts described above, Defendants, through the acts of their officers, agents, employees and sales representatives knowingly presented or caused to be presented to Cook County, Illinois fraudulent claims for payment in violation of Cook County False Claims Act, as set out in County Resolution No. 03-R-394.

277. In performing the acts described above, Defendants, through the acts their officers, agents, employees and sales representatives, knowingly made or caused to be made or used a false record or statement to get a false claim paid or approved by Cook County in violation of the Cook County False Claims Act, as set out in County Resolution No. 03-R-394.

278. Cook County, unaware of the foregoing circumstances and conduct of the Defendants, made full payments which resulted in its being damaged in an amount to be determined.

279. Cook County is therefore entitled to treble damages and civil recoveries for each and every false or fraudulent claim, record or statement made, used, presented, or caused to be made, used or presented by the Defendants.

PRAYER FOR RELIEF

WHEREFORE, Relator respectfully requests this Court to enter judgment against Defendants as follows:

a. That the United States be awarded damages in the amount of three times the damages sustained by the United States because of the false claims and fraud alleged within this Complaint, as the Civil False Claims Act, 31 U.S.C. §§ 3729 *et seq*. provides;

b. That civil penalties of $5,500 to $11,500 be imposed for each and every false claim that Defendants caused to be presented to the United States;

c. That the State of California be awarded damages in the amount of three times the damages sustained by the State of California because of the false claims and fraud alleged within this Complaint, plus a civil penalty of $10,000 for each violation of the California False Claims Act, Cal. Govt. Code §§ 12650 *et seq.*;

d. That the State of Delaware be awarded damages in the amount of three times the damages sustained by the State of Delaware because of the false claims and fraud alleged within this Complaint, plus a civil penalty for each violation of the Delaware False Claims and Reporting Act, 6 Del. C. §§ 1201 *et seq.*;

e. That the District of Columbia be awarded damages in the amount of three times the damages sustained by the District of Columbia because of the false claims and fraud alleged within this Complaint, plus a civil penalty

for each violation of the District of Columbia False Claims Act, D.C. Ann. §§ 2-308.03 *et seq.*;

f. That the State of Florida be awarded damages in the amount of three times the damages sustained by the State of Florida because of the false claims and fraud alleged within this Complaint, plus a civil penalty for each violation of the State of Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 *et seq.*;

g. That the State of Georgia be awarded damages in the amount of three time the damages sustained by the State of Georgia because of the false claims and fraud alleged within this Complaint, plus a civil penalty for each violation of the Georgia State False Medicaid Claims Act, Ga. Code Ann §§ 49-4-168 *et seq.*;

h. That the State of Hawaii be awarded damages in the amount of three times the damages sustained by the State of Hawaii because of the false claims and fraud alleged within this Complaint, plus civil penalty for each violation of the Hawaii False Claims Act - Haw. Rev. Stat. §§ 661-21 *et seq.*;

i. That the State of Illinois be awarded damages in the amount of three times the damages sustained by the State of Illinois because of the false claims and fraud alleged within this Complaint, plus civil penalty for each violation of the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §§ 175/1 *et seq.*;

j. That the State of Indiana be awarded damages in the amount of three times the damages sustained by the State of Indiana because of the false claims and fraud alleged within this Complaint, plus a civil penalty for each violation of the Indiana False Claims and Whistleblower Protection Act, Ind. Code §§ 5-11-5.5-1 *et seq.*;

k. That the State of Louisiana be awarded damages in the amount of three times the damages sustained by the State of Louisiana because of the false claims and fraud alleged within this Complaint, plus a civil penalty for each violation of the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. §§ 46:437.1 *et seq.*;

l. That the State of Massachusetts be awarded damages in the amount of three times the damages sustained by the State of Massachusetts because of the false claims and fraud alleged within this Complaint, plus a civil penalty for each violation of the Massachusetts False Claims Law, Mass. Gen. Laws Ch. 12 §§ 5A *et seq.*;

m. That the State of Michigan be awarded damages in the amount of three times the damages sustained by the State of Michigan because of the false claims and fraud alleged within this Complaint, plus a civil penalty for each violation of the Michigan Medicaid False Claims Act, Mich. Comp. Laws §§ 400.601 *et seq*.;

n. That the State of Montana be awarded damages in the amount of three times the damages sustained by the State of Montana because of the false claims and fraud alleged within this Complaint, plus a civil penalty for

each violation of the Montana False Claims Act, Mon. Stat. §§ 17-8-401 *et seq*.;

o. That the State of Nevada be awarded damages in the amount of three times the damages sustained by the State of Nevada because of the false claims and fraud alleged within this Complaint, plus a civil penalty for each violation of the Nevada False Claims Act, Nev. Rev. Stat. §§ 357.020 *et seq.*;

p. That the State of New Hampshire be awarded damages in the amount of three times the damages sustained by the State of New Hampshire because of the false claims and fraud alleged within this Complaint, plus a civil penalty for each violation of the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. §§ 167:61-b *et seq.*;

q. That the State of New Jersey be awarded damages in the amount of three times the damages sustained by the State of New Jersey because of the false claims and fraud alleged within this Complaint, plus a civil penalty for each violation of the State of New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 *et seq.*;

r. That the State of New Mexico be awarded damages in the amount of three times the damages sustained by the State of New Mexico because of the false claims and fraud alleged within this Complaint, plus a civil penalty for each violation of the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 *et seq.,* and/or each violation of the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 *et seq.*;

s. That the State of New York be awarded damages in the amount of three times the damages sustained by the State of New Mexico because of the false claims and fraud alleged within this Complaint, plus a civil penalty for each violation of the New York False Claims Act, N.Y. Finance Law §§ 187 *et seq.*;

t. That the State of Oklahoma be awarded damages in the amount of three time the damages sustained by the State of Oklahoma because of the false claims and fraud alleged within this Complaint, plus a civil penalty for each violation of the Oklahoma Medicaid False Claims Act, 63 Ok. Stat. Ann. §§ 5053 *et seq*.;

u. That the State of Rhode Island be awarded damages in the amount of three times the damages sustained by the State of Rhode Island because of the false claims and fraud alleged within this Complaint, plus a civil penalty for each violation of the Rhode Island State False Claims Act, R.I. Gen. Laws §§ 9-1.1-1 *et seq.;*

v. That the State of Tennessee be awarded damages in the amount of three times the damages sustained by the State of Tennessee because of the false claims and fraud alleged within this Complaint, plus a civil penalty for each violation of the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 *et seq.*;

w. That the State of Texas be awarded damages in the amount of three times the damages sustained by the State of Texas because of the false claims and fraud alleged within this Complaint, plus a civil penalty of $10,000 for

each violation of the Texas False Claims Act, Tex. Hum. Res. Code Ann. §§ 36.039 *et seq.* and §§ 36.002 *et seq.*;

x. That the State of Virginia be awarded damages in the amount of three times the damages sustained by the State of Virginia because of the false claims and fraud alleged within this Complaint, plus a civil penalty for each violation of the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 *et seq.*;

y. That the State of Wisconsin be awarded damages in the amount of three times the damages sustained by the State of Wisconsin because of the false claims and fraud alleged within this Complaint, plus a civil penalty for each violation of the Wisconsin False Claims for Medical Assistance Act, Wis. Stat. §§ 20.931 *et seq*.;

z. That the City of Chicago be awarded damages in the amount of three times the damages sustained by the City of Chicago because of the false claims and fraud alleged within this Complaint, plus a civil penalty for each violation of the city of Chicago False Claims Act §§ 1-22-010 *et seq.*;

aa. That the City of New York be awarded damages in the amount of three times the damages sustained by the City of New York because of the false claims and fraud alleged within this Complaint, plus a civil penalty of $10,000 for each violation of the New York City False Claims Act Local Law 53 of 2005, §§ 7-801 *et seq.*

bb. That Cook County, Illinois be awarded damages in the amount of three times the damages sustained by the County because of the false claims and

fraud alleged within this Complaint, plus a civil penalty of $10,000 for each violation of the Cook County False Claims Act, Resolution No. 03-R-394.

cc. That pre- and post-judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which Relator necessarily incurred in bringing and presenting this case;

dd. That Relator be awarded the maximum amounts allowed pursuant to the False Claims Act and State statutes as set forth herein;

ee. That Relator be awarded his attorneys' fees, expenses and costs allowed pursuant to the False Claims Act and State statutes as set forth herein; and,

ff. That this Court award such other and further relief as it deems proper.

DEMAND FOR A JURY TRIAL

Relator demands a jury trial on all claims alleged herein.

Respectfully submitted,

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Dated: October 26, 2010

By: /s/ Robin Page West

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Dated: October 26, 2010

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Dated: October 26, 2010

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